

AMENDMENT UNDER 37 C.F.R. § 1.111  
U.S. Appln. No. 10/649,719  
Attorney Docket No.: Q77115

### **REMARKS**

Claims 1-8 are all the claims pending in the application. By this Amendment, Applicant editorially amends claims 1-4, 7, and 8 to cure minor informalities. In addition, Applicant adds claims 9-16, which are clearly supported throughout the specification.

#### **I. Summary of the Office Action**

Claims 1-8 presently stand rejected.

#### **II. Preliminary Matters**

The Examiner has acknowledged Applicant's claim to foreign priority and has indicated receipt of the certified copy of the priority document filed on August 28, 2003. The Examiner has returned the initialed form PTO/SB/08 submitted with the Information Disclosure Statement filed on January 30, 2004.

The Examiner has not indicated acceptance of the drawings filed with the application on August 28, 2003. Applicant respectfully requests the Examiner to indicate acceptance of the drawings.

#### **III. Claim Rejections under 35 U.S.C. § 112**

Claims 1-4, 7, and 8 are rejected under 35 U.S.C. § 112, second paragraph. Applicant respectfully requests the Examiner to withdraw these rejections in view of the self-explanatory claim amendments being made herein.

With respect to the Examiner's rejection of claims 2, 4, 7, and 8 for allegedly reciting improper antecedent basis for "the forcible flowing," Applicant respectfully traverses in view of the following comments. There are sufficient antecedent basis for the phrase "the forcible

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flowing” because prior to this phrase, claims 2, 4, 7, and 8 recite “forcibly caused to flow.”

“Forcibly caused to flow” provides the antecedent basis for “the forcible flowing.” In view of the foregoing, Applicant respectfully requests the Examiner to withdraw this rejection of claims 2, 4, 7, and 8.

IV. Claim Rejections under 35 U.S.C. § 102

Claims 5-8 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,846,638 to Shipwash (hereinafter “Shipwash”). Applicant respectfully traverses this rejection in view of the following comments.

The Examiner contends that Shipwash discloses each feature of independent claim 5.

This rejection is not supportable for at least the following reasons. Of these rejected claims, only claim 5 is independent. Independent claim 5, among a number of unique features, recites:

a reaction apparatus comprising:

a reaction vessel, which is provided with a support section for releasably supporting a biochemical analysis unit within the reaction vessel...

flowing means for causing a reaction liquid containing the enzyme-labeled antibody to flow within the reaction vessel,

wherein the flowing means forcibly causes the reaction liquid containing the enzyme-labeled antibody to flow such that the reaction liquid containing the enzyme-labeled antibody flows across each of the porous adsorptive regions of the biochemical analysis unit.

The Examiner contends that the microfluidic system has channels, chambers and wells, which allegedly releasably support a biochemical analysis unit (*see* pages 3-4 of the Office Action).

Applicant respectfully disagrees. A reaction vessel is part of a reaction apparatus. If, as alleged by the Examiner, the microfluidic system is the reaction vessel (*see* pages 3-4 of the Office

Action), then Shipwash fails to disclose or suggest a reaction apparatus, as set forth in claim 1. Moreover, one of ordinary skill in the art would not view a microfluidic system of Shipwash (that comprises a number of channels, chambers, etc) as a reaction vessel. In short, a microfluidic system of Shipwash, as a whole, is not a reaction vessel.

Moreover, the channels, chambers, and wells of Shipwash, only contain beads, which are used to immobilize the proteins or nucleic acids (especially tRNAs). The beads, however, include chemically or physically crosslinked gels and porous or nonporous resins such as polymeric or silica based resins (col. line 62 to col. 41, line 14) and as such do not releasably support the biomolecule. In short, gels or resins only immobilize the molecule but do not releasably support the biomolecule.

Furthermore, Shipwash only discloses that that the amino acids maybe transported through reaction channels from separate reservoirs by microfluidic pumping (col. 29, lines 4 to 23). In other words, Shipwash only discloses transporting amino acids through the reaction channels via pump and not forcibly flowing enzyme-labeled antibody across each of the porous adsorptive regions of the biochemical analysis unit.

The Examiner further contends that since the micropumps of Shipwash (col. 20, lines 55 to 57) ***are capable*** of producing a pressurized flow, Shipwash discloses the flowing means forcibly flowing the enzyme-labeled antibody across each of the porous adsorptive regions of the biochemical analysis unit. In Shipwash, however, the actual amino acids are being pumped through various reaction channels. In short, Shipwash does not disclose forcibly flowing enzyme-labeled antibody (the reaction liquid) across each of the porous adsorptive regions.

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Therefore, for all the above reasons, independent claim 5 is patentable. Claims 6-8 are patentable at least by virtue of their dependency on claim 5.

V. Claim Rejections under 35 U.S.C. § 103

Claims 1 and 3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Shipwash in view of U.S. Patent No. 4,230,683 to Decker et al. (hereinafter “Decker”). Applicant respectfully traverses this rejection in view of the following comments.

Independent claims 1 and 3, in some variation, recite: “at a time at which the enzyme-labeled antibody is subjected to the specific binding with the labeled receptor or the labeled ligand, ..., a reaction liquid containing the enzyme-labeled antibody is forcibly caused to flow such that the reaction liquid containing the enzyme-labeled antibody flows across each of the porous adsorptive regions of the biochemical analysis unit.”

As explained above with respect to claim 5, Shipwash does not disclose or suggest having the reaction liquid forcibly flow across each of the porous adsorptive regions. Furthermore, Shipwash clearly fails to disclose or suggest forcibly flowing the reacting liquid at the time in which the enzyme labeled antibody is subject to binding with labeled receptor or ligand. Decker fails to cure the deficient disclosure of Shipwash.

For at least these exemplary reasons, claims 1 and 3 are patentable over the combined disclosure of Shipwash and Decker.

In addition, independent claim 3 recites: “at a time at which the labeled receptor or the labeled ligand having been labeled with the labeling substance is subjected to the specific binding with the ligands or the receptors, ..., a reaction liquid containing the labeled receptor or

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the labeled ligand, ..., is forcibly caused to flow such that the reaction liquid containing the labeled receptor or the labeled ligand flows across each of the porous adsorptive regions of the biochemical analysis unit.”

Shipwash fails to disclose or suggest forcibly flowing a reaction liquid with labeled receptor or ligand across the porous member when the labeled receptor or ligand is subject to specific binding. In other words, Shipwash does not disclose or suggest forcibly flowing different reaction liquids at two times. In Shipwash, the actual biomolecule (amino acids) flows into various reaction chambers and channels. Decker does not cure the deficient disclosure of Shipwash, as there is no forcible flowing disclosed in Decker.

For at least this additional exemplary reason, claim 3 is patentable over the combined disclosure of Shipwash and Decker.

Claims 2 and 4 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Shipwash in view of Decker, and further in view of U.S. Patent No. 6,490,034 to Woias et al. (hereinafter “Woias”). Applicant respectfully traverses in view of the following comments.

Claims 2 and 4 depend on claims 1 and 3 respectively. It was already demonstrated that Shipwash and Decker do not disclose or suggest each and every unique feature of claims 1 and 3. Woias does not cure the deficient disclosure of Shipwash and Decker. Accordingly, claims 2 and 4 are patentable at least by virtue of their dependency.

In addition, one of ordinary skilled in the art would not have and could not have combined Shipwash and Woias in the manner suggested by the Examiner. Shipwash discloses pumping the amino acids through the chambers and the reaction channels, which are then

immobilized on the surfaces of the channels and chambers (col. 29, lines 15 to 23). Woias, on the other hand, discloses pumping in a reagent (col. 4, lines 39 to 46). One of ordinary skill in the art would pump the amino acids or the reagents. In other words, the combination results in an unworkable device. At the very least, pumping the reagents (reaction liquid) of Woias as opposed to the amino acids (the sample being detected) of Shipwash would significantly change the principle of operation of Shipwash. In short, one of ordinary skill in the art would not have been motivated to combine the references in the manner suggested by the Examiner.

Moreover, the Examiner alleges that stopping the forcible flow for a period of time longer than the forcible flow is an optimum workable range (*see* page 12 of the Office Action). Applicant respectfully disagrees. Stopping the forcible flow for a period of time longer than the forcible flow allows optimum detection of the labeled receptor or the labeled ligand with a low amount of labeled receptor or the labeled ligand (pages 8, 28, and 33-36 of the specification). Accordingly, the stopping time is not simply an optimum workable range but one of many unique features of the claimed invention.

For at least these additional exemplary reasons, claims 2 and 4 are patentable over the combined disclosure of Shipwash, Decker, and Woias.

#### VI. New Claims

In order to provide more varied protection, Applicant adds claims 9-16. Claims 9-13 are patentable at least by virtue of their dependency on claim 5, claim 14 is patentable at least by virtue of its dependency on claim 1, and claims 15 and 16 are patentable at least by virtue of their dependency on claim 3.

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VII. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly invited to contact the undersigned attorney at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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